(2) *Loss on drying.* Proceed as directed in § 436.200(b) of this chapter.

[39 FR 19134, May 30, 1974, as amended at 41 FR 10886, Mar. 15, 1976; 47 FR 23710, June 1, 1982; 50 FR 19920, May 13, 1985]

§ 449.550h Nystatin lotion.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Nystatin lotion is composed of nystatin with one or more suitable and harmless suspending agents, emulsifiers, surfactants, and preservatives in a suitable and harmless vehicle. Each milliliter contains 100,000 units of nystatin. Its potency is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of units of nystatin that it is represented to contain. Its pH is not less than 5.5 and not more than 7.5. The nystatin used conforms to the standards prescribed by § 449.50(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The nystatin used in making the batch for potency, loss on drying, pH, and identity.

(*b*) The batch for potency and pH.

(ii) Samples required:

(*a*) The nystatin used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of five immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.105 of this chapter, preparing the sample for assay as follows: Place an accurately measured representative portion of the sample into a high-speed glass blender jar containing sufficient dimethylformamide to give a convenient concentration. Blend for 3 to 5 minutes. Remove an aliquot and dilute with sufficient dimethylformamide to yield a stock solution containing 400 units of nystatin per milliliter (estimated). Further dilute with 10 percent potassium phosphate buffer, pH 6.0 (solution 6), to the reference concentration of 20 units of nystatin per milliliter (estimated).

(2) *pH.* Proceed as directed in § 436.202 of this chapter, using the undiluted sample.

[40 FR 3766, Jan. 24, 1975, as amended at 50 FR 19920, May 13, 1985]

Subpart G—Vaginal Dosage Forms

§ 449.610 Candicidin vaginal dosage forms.

§ 449.610a Candicidin vaginal ointment.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Candicidin vaginal ointment is composed of candicidin and a suitable ointment base. It contains 0.6 milligram of candicidin per gram. Its potency is satisfactory if it is not less than 90 percent and not more than 140 percent of the number of milligrams of candicidin that it is represented to contain. Its moisture content is not more than 0.1 percent. The candicidin used conforms to the requirements of § 449.10(a)(1).

(2) *Labeling.* It shall be labeled in accordance with the requirements of § 432.5 of this chapter.

(3) *Requests for certification; samples.* In addition to the requirements of § 431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on:

(*a*) The candicidin used in making the batch for potency, loss on drying, pH, and identity.

(*b*) The batch for potency and moisture.

(ii) Samples required:

(*a*) The candicidin used in making the batch: 10 packages, each containing approximately 300 milligrams.

(*b*) The batch: A minimum of five immediate containers.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in § 436.106 of this chapter, preparing the sample for assay as follows: Place an accurately weighed representative portion of the sample into a separatory funnel containing approximately 50 milliliters of *n*- hexane (containing 0.1 percent butylated hydroxyanisole). Shake the sample and *n*- hexane until homogeneous. Add 15 milliliters of